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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/020,184	12/18/2001	Canakapalli Bhaktavatsala Rao	033166-004	8034

7590

09/22/2003

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EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT

PAPER NUMBER

1623

DATE MAILED: 09/22/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary

Application No.

10/020,184

Applicant(s)

RAO ET AL.

Examiner

Traviss C McIntosh

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-28,30,35 and 68-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-28,30,35 and 68-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>11</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Amendment filed July 11, 2003 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 3-14, 16-28, 30, and 35 have been amended.

Claims 1-3, 29, 31-34, and 36-67 have been cancelled.

Claims 68-70 have been added.

Remarks drawn to rejections of Office Action mailed March 25, 2003 include:

Claim objection: which has been overcome by applicants' amendments and have been withdrawn.

112 2nd paragraph rejections: which have been overcome by applicants' amendments and have been withdrawn.

103(a) rejections: which have been overcome by applicants' amendments and arguments and have been withdrawn.

An action on the merits of claims 4-28, 30, 35, and 68-70 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

It is noted that the Examiner of the U.S. Patent application SN 10/020,184 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to the Technology Center 1600, Art Unit 1623, Examiner Traviss McIntosh.

Claim Rejections - 35 USC § 112

Claims 4-28, 30, and 68-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 68 is confusing wherein the claim is drawn to a capsule with “fill material comprising a core of SAME salt selected from the group consisting of a SAME monosulphate tosylate salt and a SAME disulphate tosylate salt coated with lipophilic material, an oily matrix, antioxidants, and preservatives”. Does applicant intend the group to be 1) either SAME monosulphate tosylate or SAME disulphate tosylate, then have either of these coated with lipophilic material, an oily matrix, antioxidants, and preservatives; or does applicant intend the group to be 2) either SAME monosulphate tosylate alone or SAME disulphate tosylate coated with lipophilic material, an oily matrix, antioxidants, and preservatives? Clarity is respectfully requested. It is noted that the examiner has interpreted the claim as option 1 above.

Claims 68, 8, 11, 30 and 35 are indefinite as all these claims set forth an acronym without properly defining what is intended by the acronym. Claims 68, 8, 30, and 35 are all drawn to SAME, yet there is nothing in the claims which sets forth what SAME is intended to represent. Claim 11 is drawn to NDGA, which is not defined. Defining the acronyms in the first claim which these acronyms are used would be seen to obviate the rejection at hand.

Claim 14 is indefinite as the claim provides the limitation that claim 68 is to optionally comprise preservatives, yet claim 68 already provides the limitation that the composition comprises preservatives. It is unclear how this recitation is a further limitation to the claim from which it depends.

Claims 14 and 27 recite limitations drawn to the “soft gelatin film”. There is insufficient antecedent basis for this limitation in the claim, as claim 68, in which both claims 14 and 27 depend from, does not provide guidance to any “soft gelatin film”.

All claims which depend from an indefinite claim are also indefinite. *Ex parte Cordova, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).*

Allowable Subject Matter

Claims 68 and 35 appear to be free of the prior art of record and might be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

Claims 8, 11, 14, 27, and 30 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 4-28, 30, 35, and 68-70 are seen to be free of the prior art of record because the composition/method contains the limitation(s) of the composition being in a soft gelatin capsule with fill material of the specific SAME salts coated with a lipophilic material, which is not seen to be taught or fairly suggested by the prior art of record.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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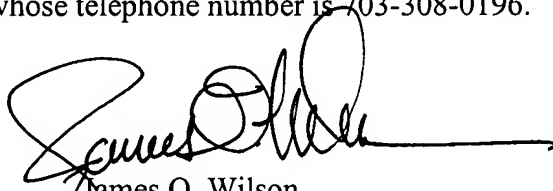
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 703-308-9479. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Traviss C. McIntosh III
September 10, 2003



James O. Wilson
Supervisory Patent Examiner
Art Unit 1623